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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,173	07/15/2003	William Howard Roark	PC25208A	9477

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,173	ROARK, WILLIAM HOWARD	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 in part, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A, wherein X_1, X_2, and X_3 are all independently of each other, represents C-R_6 and no fused tri-cyclic ring system classified in class 514, subclass 283, for example.

II. Claims 1-5 in part, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A in which exactly one of X_1, X_2, and X_3 represents N, and the other two of X_1, X_2, and X_3independently represent C-R_6, and there is no fused tri-cyclic ring system, classified in class 514, subclass 279, for example.

III. Claims 1-2 and 5 in part, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A in which exactly two of X_1 , X_2, and X_3 represent N, and the other one of X_1 , X_2, and X_3 represents C-R_6, and there is no fused tri-cyclic ring system, classified in class 514, subclass 236 or 256, for example.

IV. Claims 1 and 3-5 in part, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A in X_1 , X_2, and X_3 all independently represent C-R_6, and W_1-W_2, classified in class 514, subclass 251 , for example.

V. Claims 1 and 5 in pad, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A in which exactly one of X_1, X_2, and X_3 represents N, and the other two of X_1 , X_2, and X_3 independently represent C-R_6, and W_1-W_2, classified in class 544, subclass 251 , for example.

VI. Claims 1 and 5 in part, drawn to a combination comprising a selective inhibitor of COX-2 that is not celecoxib or valdecoxib with a compound of formula A in which exactly two of X_1 , X_2, and X_3 represent N, and the other one of X_1 , X_2, and X_3 represents C-R_6, and W_1-W_2, classified in class 544, subclass 234 or 251 , for example.

VII. Claims 6-10, drawn to a method of treating a disease comprising administering a therapeutically effective dose of a combination comprising a selective inhibitor of COX-2 that is not of valdecoxib and an allosteric carboxylic inhibitor of MMP-13, classified in class 514, subclass 248, 249, 250, 262.1, 264.1, 264.1 1 , and 266.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are separate and patentably distinct in view of being drawn to combinations comprising structurally distinct compounds. The MMP-13 inhibitors included in the various groups have unrelated structures and thus raise different issues of patentability.

This difference is illustrated by the separate classifications of the MMP-13 inhibitors in each group. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would

require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions I-VI are related to invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP j 806.05(h)). In the instant case the method of Group VII could be practiced with another materially different product, including other non-steroidal anti-inflammatory drugs such as ibuprofen or naproxen for treatment of inflammatory arthritis and joint pain. The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or

method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Group VII is not required for Groups I-VI, restriction for examination purposes as indicated is proper.

The groups above are set forth in order of precedence in the claims. Any specie/compound/composition having the distinguishing feature set forth in one of the above groups will be contained in that group regardless of the fact that it may also contain a feature set forth in a group of lower precedence.

It is considered that at Markush type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claim anticipated or obvious under 35 U.S.C. 102 nor 35 U.S.C. 103 respectively with regard to any one other of the species. Further these species are considered to be independent since they are unconnected in operation, one does not require the others for ultimate use and the specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered patentably distinct from the others on the basis of its properties. Thus, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

Further, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define each of X_1 , X_2, and X_3, C-R_6, and W_1-W_2 and n and any additional variables as required for a particular species. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states "[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.". Here, the claims recited such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 9/5/06

SVG

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER